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10/003,463	12/06/2001	Luis Enrique Fernandez Molina	024518-00001	4352

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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/003,463	MOLINA ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,27 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 27 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed September 19, 2006 in response to the Office Action of April 19, 2006, is acknowledged and has been entered. Previously pending claim 9 has been amended. Claims 1-11, 27 and 28 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained

Claim Rejections - 35 USC § 103

3. **Claims 1-10, 27 and 28 remain rejected under 35 U.S.C. 103(a)** as being unpatentable over US Patent 5,788,985, Rodriguez et al., issued 8/4/98 (IDS), in view of US Patent 4,857,637, Hammonds et al., issued 8/15/89 and Udayachander et al (Human Antibodies, 1997, 8:60-64) (see section 9 of the previous Office Action).

The claims are drawn to a pharmaceutical composition that potentiates immunogenicity of low immunogenic antigens comprising (s) one or more low immunogenic antigens and (b) a vaccine carrier consisting of very small size proteoliposomes (VSSPs), wherein the VSSPs are derived from the Outer Membrane Protein Complex (OMPC) of *Neisseria meningitides* wherein gangliosides have been incorporated into the OMPC (claim 1), wherein the low immunogenic antigen is a polypeptide (claim 2), wherein the low immunogenic antigen is a growth factor receptor (claim 3), wherein the extra cellular domains of the growth factor receptor may or may

not contain the trans-membrane region (claim 4), wherein the growth factor receptor is HER-1 (claim 5), wherein the *Neisseria meningitides* is either a wild type or genetically modified strain (claim 6), wherein the VSSPs are obtained by hydrophobically incorporating the gangliosides into the OMPC (claim 7), wherein the gangliosides are GM3 or their N-glycosylated variations (claims 8 and 28), wherein the adjuvant is an oily adjuvant and is Incomplete Freund's Adjuvant (claims 9 and 10), and wherein the composition further comprises one or more adjuvants (claim 27).

US Patent 5,788,985 teaches a pharmaceutical composition that potentiates the immunogenicity of low immunogenic antigens comprising an Outer Membrane Protein Complex (OMPC) of *Neisseria meningitides* wherein gangliosides have been incorporated into the OMPC (Examples 2-4). US Patent 5,788,985 teaches that the pharmaceutical composition increases the immune response against N-glycolsylated ganglioside, especially N-glycol GM3 (NGcGM3) which can be used for the treatment of cancer (col. 1, lines 1-12), especially breast cancer which has a higher expression of gangliosides GM3 and GD3 compared to normal breast tissue (abstract; col. 1, lines 59-63 and Example 6), hence gangliosides are targets in treatment approaches (col. 1, lines 64-66). US Patent 5,788,985 teaches the incorporation of gangliosides, including the hydrophobic incorporation of NGcGM3, into the OMPC (col. 2, lines 30-36; col. 3, lines 1-20; Example 2), wherein the OMPC would be expected to be either a wild-type or a genetically modified strain (col. 6, lines 1-3).

US Patent 5,788,985 does not teach the pharmaceutical composition further comprising the low immunogenic antigen HER-1 or Incomplete Freund's adjuvant.

US Patent 4,857,637 teaches a pharmaceutical composition comprising the polypeptide epidermal growth factor receptor (EGFR, or HER-1) as an antigen to immunize animals against the EGFR (col. 3, lines 36-43; col. 4, lines 58-63). US Patent 4,857,637 teaches that EGFR is overexpressed in malignant cells and is a desirable target for therapy (col. 3, lines 63-66; col. 4, lines 26-38). Immunization may comprise administering growth factor receptor derivatives or intact receptors (col. 4, lines 57-61). Growth factor receptors comprise extracellular, transmembrane and cytoplasmic domains, wherein immunization of a receptor comprising the extracellular domain is desirable because the extracellular domain is accessible to antibodies under *in vivo* conditions, unlike the intracellular or cytoplasmic domains (col. 8, lines 47-68). US Patent 4,857,637 teaches the immunization of growth factor receptors with an adjuvant, such as Incomplete Freund's, because poorly immunogenic proteins are rendered more immunogenic by the use of adjuvants (col. 4, lines 63-68; col. 5, lines 50-55; col. 7, lines 1-3; col. 18, lines 50-55).

Udayachander et al teach that many malignancies, such as breast cancer, overexpress EGFR and EGFR is a target for therapy (abstract).

These references suggest the importance of each of the claimed pharmaceutical composition components in stimulating an immune response to the ganglioside or EGFR antigen. However, the references are deficient in that they do not teach using these components together. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the Outer Membrane Protein Complex (OMPC) of *Neisseria meningitides* wherein ganglioside antigens have been

incorporated into the OMPC taught by US Patent 5,788,985 and the EGFR (HER-1) antigen taught by US Patent 4,857,637 in combination in order to treat malignant tumors that overexpress these two antigens, such as breast cancer, because US Patent 5,788,985 teaches that breast cancer overexpresses ganglioside GM3 and Udayachander et al teach that breast cancer overexpresses HER-1. One of ordinary skill in the art would have been motivated to use the two pharmaceutical components in combination in a method of treating a malignant tumor that overexpresses the two antigens, such as breast cancer, in view of the importance of targeting these two antigens for cancer therapy. Each of these agents had been taught by the prior art to be therapeutic targets in the treatment of malignant tumors, such as breast cancer, thus the instant situation is amenable to the type of analysis set forth in In re Kerkhoven, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is *prima facie* obvious to combine two modes of treatment, each of which is taught by the prior art to be useful for the same purpose in order to make a protocol that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. One of ordinary skill in the art would have reasonably expected to obtain effective therapeutic targeting of malignant tumors, such as breast cancer, with either or both of these agents since both had been demonstrated in the prior art to successfully illicit an immune response specific to the target cancer antigen.

Similarly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use Incomplete Freund's adjuvant in addition to the two pharmaceutical components because adjuvant is conventionally used in

pharmaceutical compositions and US Patent 4,857,637 teaches that poorly immunogenic proteins are rendered more immunogenic by the use of adjuvants such as Freund's Incomplete. One would have been motivated to add Freund's Incomplete to the pharmaceutical composition taught by the combined references in order to boost the immune response to the antigens for therapeutic purposes.

4. **Claim 11 remains rejected under 35 U.S.C. 103(a)** as being unpatentable over US Patent 5,788,985, Rodriguez et al., issued 8/4/98 (IDS), US Patent 4,857,637, Hammonds et al., issued 8/15/89 and Udayachander et al (Human Antibodies, 1997, 8:60-64), in further view of Carr et al (Melanoma Research, June 2001, 11:219-227) (see section 10 of the previous Office Action).

The claim is drawn to the composition of claim 10 wherein the Incomplete Freund's adjuvant is Montanide ISA 51.

US Patent 5,788,985, Rodriguez et al., issued 8/4/98, US Patent 4,857,637, Hammonds et al., issued 8/15/89 and Udayachander et al (Human Antibodies, 1997, 8:60-64) teach a pharmaceutical composition as set forth above. The combined references do not teach the Incomplete Freund's adjuvant is Montanide ISA 51.

Carr et al teach a pharmaceutical composition comprising Montanide ISA 51 and a very small size proteoliposomes (VSSPs), wherein the VSSPs are derived from the Outer Membrane Protein Complex (OMPC) of *Neisseria meningitides* wherein GM3 gangliosides have been incorporated into the OMPC. Carr et al teach the significant

increase in overall survival of mice inoculated with cancer cells expressing gangliosides after administration of this pharmaceutical composition (abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the Incomplete Freund's adjuvant Montanide ISA 51 with the pharmaceutical composition taught by the combined references because the combined references teach the use of Incomplete Freund's adjuvant to increase immunogenicity of antigens and Carr et al teach the use of Incomplete Freund's adjuvant Montanide ISA 51 specifically as a form of Freund's adjuvant in combination with the VSSP that successfully treated mice. One would have been motivated to use Montanide ISA 51 as a form of Freund's adjuvant in combination with the VSSP/HER-1 composition because of its demonstrated success in the lab of increasing the survival of mice with cancer expressing gangliosides.

Response to Arguments

5. Applicants argue that although Rodriguez et al discloses VSSPs, there is no disclosure in the reference that the VSSPs can be utilized to potentiate the immunogenicity of low immunogenic antigens such as growth factor receptors. In addition, there is no disclosure in any of the secondary references that the VSSPs of Rodriguez et al could potentiate the immunogenicity of low immunogenic antigens (p. 7).

The argument has been considered but is not found persuasive because the pharmaceutical composition taught by the combined references comprises the same agents as the claimed composition. The recitation of "that potentiates immunogenicity of low immunogenic antigens" is merely suggestive of an intended use and does not distinguish the claims from the prior art. The claims read on the active ingredients *per se*, which are a low immunogenic antigen, HER1, and a vaccine carrier consisting of very small size proteoliposomes (VSSPs), wherein the VSSPs are derived from the Outer Membrane Protein Complex (OMPC) of *Neisseria meningitides* wherein gangliosides have been incorporated into the OMPC.

6. Applicants argue that surprisingly, they have found that the claimed pharmaceutical composition of the present invention confers immunogenicity to peptides, polypeptides, proteins, and their DNA sequences and target cells of the vaccine just by mixing them with the VSSPs described by Rodriguez et al. The pharmaceutical compositions of the present invention show surprising immunological properties such as a dramatic ability to cause dendritic cells maturation and resorting immune-suppressed patients (p. 7-8).

The argument has been considered but is not found persuasive because Applicants have not provided or argued objective evidence showing that the properties of the claimed composition are unexpected or surprising as compared to the composition taught by the prior art.

MPEP 716.01(c) states: Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See, for example, In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by factual evidence." "[A]ppellants have not presented any experimental data showing that prior heat-shrinkable articles split. Due to the absence of tests comparing appellant's heat shrinkable articles with those of the closest prior art, we conclude that appellant's assertions of unexpected results constitute mere argument."). See also In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972); Ex parte George, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991).

MPEP 716.02(b) States: The evidence relied upon should establish "that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance." Ex parte Gelles, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992) (Mere conclusions in appellants' brief that the claimed polymer had an unexpectedly increased impact strength "are not entitled to the weight of conclusions accompanying the evidence, either in the specification or in a declaration."); Ex parte C, 27 USPQ2d 1492 (Bd. Pat. App. & Inter. 1992) (Applicant alleged unexpected results with regard to the claimed soybean plant, however there was no basis for judging the practical significance of data with regard to maturity date, flowering date, flower color, or

height of the plant.). See also In re Nolan, 553 F.2d 1261, 1267, 193 USPQ 641, 645 (CCPA 1977) and In re Eli Lilly, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) as discussed in MPEP § 716.02(c).

MPEP 716.02 states: Any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)

7. Applicants argue that the fact the immune response generated by proteins is quite different from that generated by carbohydrates is an important feature of the claimed compositions described of the present invention and has been neither suggested nor anticipated by Rodriguez et al or any other prior art (p. 8).

The argument has been considered but is not found persuasive because Applicants are arguing limitations not recited in the claims.

8. Applicants argue that two main features distinguish the invention form the cited prior art and from the state of the art: 1) using VSSPs resulted in adjuvant capacity of the protein complex that was substantially increased, with the ganglioside playing a crucial role in it; and 2) the side effect of targeting of GM3 in VSSP renders

pharmaceutical compositions with the capacity of stimulating both humoral and cell responses, particularly individuals with a deeply depressed immune system (p. 8-9).

With regards to feature 1, the argument has been considered but is not found persuasive because Applicants have not provided objective evidence showing that the results of the pharmaceutical composition combination is surprising or significant as compared to the pharmaceutical composition taught by the prior art. For example, it is unclear what a "substantial" increase in adjuvant capacity is. And it is unclear how this feature is different form the composition taught by the prior art because the prior art (particularly Rodriguez et al) includes ganglioside in the VSSPs of the pharmaceutical composition.

MPEP 716.01(c) states: Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See, for example, In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by factual evidence." "[A]ppellants have not presented any experimental data showing that prior heat-shrinkable articles split. Due to the absence of tests comparing appellant's heat shrinkable articles with those of the closest prior art, we conclude that appellant's assertions of unexpected results constitute mere argument."). See also In re Lindner, 457 F.2d 506, 508,

173 USPQ 356, 358 (CCPA 1972); Ex parte George, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991).

MPEP 716.02(b) States: The evidence relied upon should establish "that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance." Ex parte Gelles, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992) (Mere conclusions in appellants' brief that the claimed polymer had an unexpectedly increased impact strength "are not entitled to the weight of conclusions accompanying the evidence, either in the specification or in a declaration."); Ex parte C, 27 USPQ2d 1492 (Bd. Pat. App. & Inter. 1992) (Applicant alleged unexpected results with regard to the claimed soybean plant, however there was no basis for judging the practical significance of data with regard to maturity date, flowering date, flower color, or height of the plant.). See also In re Nolan, 553 F.2d 1261, 1267, 193 USPQ 641, 645 (CCPA 1977) and In re Eli Lilly, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) as discussed in MPEP § 716.02(c).

MPEP 716.02 states: Any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)

With regards to feature 2: "the side effect of targeting of GM3 in VSSP renders pharmaceutical compositions with the capacity of stimulating both humoral and cell responses, particularly individuals with a deeply depressed immune system" the argument has been considered but is not found persuasive because Applicants have

not shown how the claimed pharmaceutical composition is different from that taught by the prior art. The composition taught by the prior art also encompasses GM3 incorporated into VSSPs, so it is unclear how the claimed composition is different from that taught by the prior art. Further, "the capacity of stimulating both humoral and cell responses, particularly individuals with a deeply depressed immune system" is a limitation not recited in the claims.

9. Applicants argue that the mere identification of a desirable target (by Udayachander et al) does not suggest any real probability in arriving at a result that will be useful, with regards to Hammonds et al teaching a pharmaceutical composition comprising HER1 to immunize animals against HER1 (p. 9).

The argument has been considered but is not found persuasive because Applicants are arguing individual references. Udayachander et al was provided to teach that breast cancer expresses HER1 and is a target for therapy, hence the composition taught by Hammonds et al to elicit an immune response against HER1 would target breast cancer for therapy.

10. Applicants argue that Hammonds et al teaches immunizing an animal against a cell surface receptor coupled to a carrier protein and using an adjuvant, wherein the immunization can lead to the recovery of specific antibodies form the serum of the immunized animal, and in Hammond et al, the efficiency of the immune response is not

crucial. Even when the immune response against the specific antigen was low, lymphocytes producing antibodies against the antigen could be isolated. To the contrary, the present invention relates to a composition for increasing the immunogenicity of poorly immunogenic antigens (p. 9). Applicants argue that Hammonds et al does not describe any immune response obtained when immunizing with the fragments (p. 9).

The argument has been considered but is not found persuasive because the claimed composition and the composition of the prior art comprise the same agents and Applicants have not shown how the claimed composition is different from the composition taught by the prior art.

11. Applicants argue that although one of ordinary skill in the art may be motivated to use the two components in combination in a method of treating a malignant tumor that overexpresses the two antigens, there is no expectation of success in the art, for example, several approaches for passive therapy in which EGFR has been targeted with monoclonal antibodies as well as for the treatment with tyrosine kinase inhibitor drugs, have failed. Contrary to these failures in the prior art, the use of the claimed pharmaceutical compositions of the present invention for EGFR based active immunotherapy is successful, as published by Ramirez et al (Int J Cancer, 2006, 119:2190-2199).

The argument has been considered but is not found persuasive. The prior art references teach that the antigens are used for immunization and would treat breast

cancer, hence would be expected to be successful combined as a pharmaceutical for the same purpose. Applicants provide examples of antibody therapy and tyrosine kinase drugs as unsuccessful in treatment, however, these examples are not drawn to a pharmaceutical composition comprising EGFR or the extracellular domain and operate by a different mechanism. Regardless of success, the components of the claimed pharmaceutical composition each have been taught by the prior art as immunizing agents, each for treating breast cancer, and one would be motivated to combine the agents for the reasons set forth above.

Further, Ramirez et al does not teach success of the scope of the broadly claimed invention. Ramirez et al teaches only EGFR and VSSPs, not any low-immunogenic antigen and VSSP adjuvant.

12. Applicants argue that claim 11 rejected in further view of Carr et al does not render obvious the subject matter of claims 1-10, 27 and 28 as previously stated and Carr et al does not supply any of the deficiencies of the cited primary and secondary references.

The arguments have been considered but are not found persuasive. The combined references teach the claimed composition as set forth above, hence the only deficiency supplied by Carr et al is the presence of a specific Freund's adjuvant in the composition.

13. All other rejections recited in the Office Action mailed April 19, 2006 are hereby withdrawn.

14. No claim is allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. ' 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. ' 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642

SHANON A. FOLEY
SUPERVISORY PATENT EXAMINER